



PROGETTO MATTONE INTERNAZIONALE

**Progetto Dir-Mi:
azioni a supporto del processo di implementazione della
Direttiva 2011/24/UE**

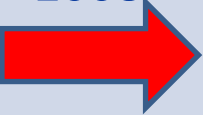
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The European Commission has undertaken several initiatives, from **basic research to public health**, for:

- improving **recognition, visibility and traceability** of RD
- supporting **national plans** for RD in EU Member States
- strengthening **European-level cooperation and coordination to share knowledge and expertise** and ensure equal access for patients to care
- encouraging more **research** into rare diseases

| | | |
|---|--|--|
| 1999 -2003 | Community action programme on Rare Diseases | <ol style="list-style-type: none"> 1. to ensure a high level of health protection in relation to RDs 2. to improve knowledge and facilitate access to information about RDs |
| 2000 | Orphan Medicinal Product Regulation N° 141/2000 (European Parliament) | <ol style="list-style-type: none"> 1. to set up the criteria for orphan designation 2. to describe the incentives (e.g. 10-year market exclusivity, protocol assistance, access to the Centralised Procedure for Marketing Authorisation) 3. to encourage research, development and marketing of medicines for RDs |
| 2008  | Commission Communication COM (2008) 679/2 to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on Rare diseases | Europe's challenges creating an integrated approach for the EU action in the field of rare diseases. |
| 2008-2013 | EU Health Programme | Rare diseases as a priority |

| Period | Action | Aim |
|--|--|---|
|  | Council Recommendation on a European action in the field of rare diseases (2009/C 151/02) | Actions at national level to implement the EU efforts (e.g. National plans for rare diseases) |
| 2011 2013- ... | Framework Programme 7th Horizon 2020 .. | The main focus of the Health theme in the RD area are Europe-wide studies of natural history, pathophysiology, and the development of preventive, diagnostic and therapeutic interventions. |
|  | Directive 2011/24/EU -European Parliament and of the Council on the application of patients' rights in cross-border healthcare | To establish rules for facilitating access to safe and high quality cross-borders health care in the EU |

COUNCIL RECOMMENDATION
of 8 June 2009
on an action in the field of rare diseases
(2009/C 151/02)

... **RECOMMENDS THAT MEMBER STATES:**

Elaborate and adopt a plan or strategy as soon as possible, *preferably by the end of 2013 at the latest*

Take action to integrate current and future initiatives at local, regional and national levels into their plans or strategies for a comprehensive approach

Define a limited number of priority actions within their plans or strategy, with objectivs and follow-up mechanisms

Take note of the development of guidelines and recommendations of the ongoing european project EUROPLAN (www.europlanproject.eu)

EU Council Recommendation and EUROPLAN Recommendation

- AREA 1. plans and strategies in the field of rare diseases
- AREA 2. adequate definition, codification and inventorying
- AREA 3. research on rare diseases
- AREA 4. **centres of expertise and european reference networks for rare diseases**
- AREA 5. gathering the expertise on rare diseases at european level
- AREA 6. empowerment of patient organizations
- AREA 7. sustainability

EUCERD

The **European Union Committee of Experts on Rare Diseases** is charged with aiding the European Commission with the preparation and implementation of Community activities in the field of rare diseases, in cooperation and consultation with the specialised bodies in Member States, the relevant European authorities in the fields of research and public health action and other relevant stakeholders acting in the field. [Read more](#)



New EUCERD
Recommendation on
RD European



Rare Disease Day
2013 – Watch the
video!



Summary report of 7th
EUCERD meeting now
available



Country editions of the
2012 EUCERD State of the
Art Report available

www.eucerd.eu



EUCERD RECOMMENDATIONS
on
RARE DISEASE EUROPEAN
REFERENCE NETWORKS (RD
ERNS)

www.eucerd.eu
www.euoplanproject.eu



EUCERD RECOMMENDATIONS



QUALITY CRITERIA FOR CENTRES OF EXPERTISE FOR RARE DISEASES IN MEMBER STATES

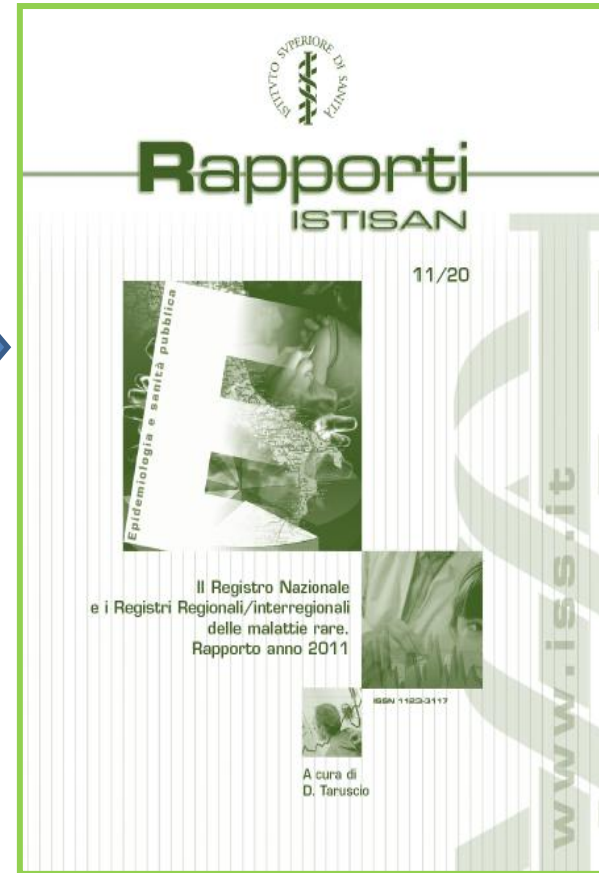
www.eucerd.eu

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REGISTRO NAZIONALE MALATTIE RARE (D.M. 279/2001)



REGISTRO
NAZIONALE
MALATTIE RARE



PRESIDI
CENTRI

REGISTRI REGIONALI E
INTERREGIONALI

DATA SET
(OGNI 6 M /1 ANNO)



GRAZIE DELL'ATTENZIONE